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Date of Signature: October 9, 2007

**PATENT**  
BHG&L Case 8627/405

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Kieran P. J. Murphy	:	Cook Case PA-5281
		:	
Serial No.:	09/594,685	:	Group Art Unit: 3732
		:	
Filed:	June 16, 2000	:	Examiner: Michael J. Araj
		:	
For:	APPARATUS FOR	:	Confirmation No. 2321
	STRENGTHENING	:	
	VERTEBRAL BODIES	:	

**REPLY BRIEF ON APPEAL TO THE  
BOARD OF PATENT APPEALS AND INTERFERENCES**

COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Appellants' Second Substitute Main Brief was filed June 14, 2007. This Reply Brief responds to the Examiner's Answer mailed September 12, 2007.

**EXAMINER'S SUMMARY OF CLAIMED SUBJECT MATTER**

The Examiner states (Examiner's Answer, Section (5), page 2) that the summary of claimed subject matter contained in Appellant's Main Brief (Section (6), pages 4-13) is correct.

### **EXAMINER'S GROUNDS OF REJECTION**

The "Grounds of Rejection" specified by the Examiner (Examiner's Answer, Section (9), pages 4-7) are essentially identical to the "Detailed Action" in the Final Rejection mailed November 15, 2004, pages 2-5.

### **EXAMINER'S RESPONSE TO ARGUMENT**

#### **(a) Claims 22-23**

The first "Response to Argument" specified by the Examiner (Examiner's Answer, Section (10)(a), pages 7-8) states that the Amendments filed February 5, 2006, were denied entry and affirmed by the directors of Technology Center 3700.

To expand on that statement, the Examiner stated at page 10 of the Final Rejection that "Claims 22 and 23 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in [the Final Rejection] and to include all of the limitations of the base claim and any intervening claims." Those rejections stated that it was unclear if the recited components were present in both trays collectively, or individually; but that for purpose of examination, it was assumed that each tray included all components.

The Amendment filed February 5, 2006, would have overcome the 35 USC 112 rejections and included all of the limitations of the base claim and any intervening claims, but the Examiner then stated (Advisory Action of March 10, 2005) that the proposed Amendment would not be entered because it would require new search, and because it raised the question of new matter. A timely Request for Reconsideration of the denial of entry of the Amendment was filed on April 5, 2005, but no response to the Request has been made by the Examiner. A timely Petition under 37 CFR 1.181 was filed May 9, 2005, requesting review of the denial of entry of the Amendment. The petition was "dismissed" on November 21, 2006, by a decision on the merits, stating that inquiry should be directed to Allan N. Shoap, Special Programs Examiner. It was signed by Karen M. Young for Frederick R. Schmidt, Director for Technology Center 3700. There is no indication that Mr. Schmidt ever saw or approved the decision.

No one has adequately explained why Claims 22 and 23 were considered to be allowable if rewritten; but when rewritten in independent form and to make explicit the assumption made by the Examiner as to the meaning of the claims, to overcome the 35 USC 112 rejections, they required further search.

**(b) Claims 17-19**

The second “Response to Argument” specified by the Examiner (Examiner’s Answer, Section (10)(b), pages 8-11) is essentially identical to the first portion of the “Response to Argument” in the Final Rejection mailed November 15, 2004, pages 5-8.

**(c) Claims 1-16, 20 and 21**

The third “Response to Argument” specified by the Examiner (Examiner’s Answer, Section (10)(c), pages 11-12) is a minor revision, adding no new substance, to the latter portion of the “Response to Argument” in the Final Rejection mailed November 15, 2004, pages 8-9.

It is thus apparent that the Examiner has no answer to Appellants’ Second Substitute Main Brief, and he can only repeat what was said before. In particular, the Examiner has no response or disagreement with the following statements:

(1) “No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claims 1-16.” (Second Substitute Main Brief at page 6).

(2) “Lazarus, the reference applied to allegedly anticipate Claims 17-19, does not teach ‘vertebroplasty injection components’ as recited in claim 17. Furthermore, no prior art reference or combination of references applied by the Examiner teaches or suggests the two-tray configuration claimed in claims 17-19, arranged so that the first tray of components can be used to perform a first vertebroplasty injection, and then the second tray of components can either (a) be used to perform a second vertebroplasty injection, or (b) remain sterile for use in another vertebral body.” (Second Substitute Main Brief at page 8).

(3) “No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claim 20.” (Second Substitute Main Brief at page 9).

(4) “No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claim 21.” (Second Substitute Main Brief at page 10).

(5) “No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in Claim 22 or in Claim 23; and in fact the Examiner indicated in the Final Rejection mailed November 15, 2004, that Claims 22 and 23 were considered indefinite and rejected under 35 USC 112, second paragraph, in that it was unclear whether the recited components were present in the first and second tray in combination, or if each of the first and second trays contained the recited components; but that for examination purposes, the claims had been construed to recite that each of the first and second trays contained the recited components (page 2); and that Claims 22 and 23 would be allowable if rewritten to overcome the rejection under 35 USC 112, second paragraph, and to include all of the limitations of the base claim and any intervening claims (page 10.)” (Second Substitute Main Brief at page 13).

The Examiner not only did not deny these five statements, as noted above on page 1, he acknowledged that they were correct (Examiner’s Answer, Section (5), page 2 – “The summary of claimed subject matter contained in [Appellant’s Second Substitute Main] brief is correct.”).

The Examiner also has no response or disagreement with the following statements:

(6) “[T]he Examiner’s interpretation [of Claims 22 and 23, which were construed to recite that each of the first and second trays contained the recited components] is the only reasonable one, and ... the Claims are not indefinite. ... The rejection should be reversed, because the interpretation chosen by the Examiner for the purpose of examination is the only reasonable one.” (Second Substitute Main Brief at pages 14 and 15).

(7) “The Examiner does not take proper account of a point made in the Appeal Brief filed January 12, 2004, and reiterated in the last two Amendments, namely that the “Lazarus

apparatus does not have ‘vertebroplasty injection components’, recited in claim 17, lines 3 and 5, in either tray.” ” (Second Substitute Main Brief at page 15).

(8) “The Examiner ignores the explanation in the Declaration why the Lazarus components are not “vertebroplasty injection components”, dismissing it as “opinion” of a party who has an interest in the outcome of the case, and lacking in “facts”. The Examiner ignores the facts recited in the Declaration in Paragraphs 7-12, *e.g.*, that vertebroplasty injection components are a different size than the Lazarus needles.” (Second Substitute Main Brief at page 16). The “Declaration” referred to is the Declaration Under 37 CFR 1.132 of Dr. Kieran Murphy, explaining that the Lazarus apparatus does not have “vertebroplasty injection components”, recited in claim 17, lines 3 and 5, in either tray, as that term is understood by persons of ordinary skill in the art. (See Declaration at pages 3-5, paragraphs 7-12.) A copy of the Declaration is Appendix C of Appellant’s Second Substitute Main Brief.

(9) “[A]s explained in the Declaration, the recitation “vertebroplasty injection components” is more than an intended use; it designates for example needles sufficiently robust for injection of bone cement. The Examiner says “facts” are events, acts or occurrences which have actually taken place, and indeed, that is what *historical* facts are. However, it is also a fact, as pointed out in the Declaration, that vertebroplasty injection needles need to be sufficiently robust for injection of bone cement. So the Examiner ignores the facts stated in the Declaration, and *based on no facts at all*, elevates his own opinion over that of the expert. This is error.” (Second Substitute Main Brief at page 16).<sup>1</sup>

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<sup>1</sup> With respect to the propriety of the Examiner or even the Board of Patent Appeals and Interferences elevating their own opinion over that of expert evidence of record, the Second Substitute Main Brief discussed, at pages 16-17, the recent precedential decision of the Court of Appeals for the Federal Circuit, *Brand v. Miller*, 487 F.3d 862, 82 USPQ2d 1705 (Fed. Cir. 2007). The Court held “that, in the context of a contested case, it is impermissible for the Board to base its factual findings on its expertise, rather than on the evidence in the record, although the Board’s expertise appropriately plays a role in interpreting record evidence.” 487 F.3d at 869, 82 USPQ2d at 1710. The Court went on to say “We do not – and need not – decide here the extent to which the Board in *ex parte* proceedings is so limited.” *Id.* The Examiner has not, however, explained why the Examiner should base his factual findings (that “it is clear that each tray [of Lazarus] include[s] a[n] injection component and they can perform a function in spinal surgery if one so desire[s].”) on his expertise, rather than on the evidence in the record (the explanation in the Declaration why the Lazarus components are not “vertebroplasty injection components”).

(10) “The Declaration ... explains why the *combinations* claimed in Claims 1-16, 20 and 21 would not have been obvious to a person of ordinary skill in the art, either from Vagley alone or from Vagley in view of the eleven secondary references applied in another rejection. (See Declaration at page 5, paragraphs 13-14.)” (Second Substitute Main Brief at page 18).

### CONCLUSION

Claims 17-19, 22 and 23 recite “vertebroplasty injection components”, which are not present in the Lazarus patent. Applicant has filed the Declaration of Dr. Kieran Murphy, showing that the Lazarus patent does not teach “vertebroplasty injection components” as that term is understood by persons of ordinary skill in the art. The Examiner has not justified elevating his opinion over that of Dr. Murphy.

Claims 1-16, 20 and 21 recite combinations, which neither Vagley nor any of the secondary references teach or suggest.

Claims 22 and 23 were indicated to be allowable if rewritten to overcome formal rejections and eliminate reference to rejected claims. Claims 22 and 23 were proposed to be amended to overcome formal rejections and eliminate reference to rejected claims, but have not been allowed.

All rejections applied by the Examiner should therefore be REVERSED.

Respectfully submitted,

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